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Daniel W. Chan

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EXAMINER

HARRIS, ALANA M

ART UNIT

PAPER NUMBER

1643

MAIL DATE

DELIVERY MODE

07/07/2010

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.



## DETAILED ACTION

### *Response to Arguments*

1. Claims 3-5, 9-12, 34, 39, 40 and 62 are pending.

Claim 40, drawn to non-elected inventions are withdrawn from examination.

Claims 3-5, 9-12, 34, 39 and 62 are examined on the merits.

### *Claim Objections*

2. Claim 3 is objected to because of the following informality: it is not clear if Applicants have misnumbered the markers listed in the claim. Moreover, it is not clear if the listed as Marker VII on line 10 of the claim should be listed as Marker VI. Clarification is required.

### *Maintained Grounds of Rejection*

#### *Claim Rejections - 35 USC § 112*

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. The **NEW MATTER REJECTION** of claims 3-5, 9-12, 34, 39 and 62 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is maintained.

Applicants continue to assert the amendment submitted February 11, 2008 made to claim 3 to recite "wherein an increase in the levels of one or more of Markers II and III, or a decrease in the levels of one or more of Markers I, IV, V or VII is indicative that the subject has ovarian cancer." is supported by the specification, see Remarks submitted March 31, 2010. In addition to the previously cited Example 1 found on page 47, lines 28-31 wherein it is cited

"...peaks at 9.2kD [Marker II], 19.8kD [Marker III], and 60kD showed higher expression levels on average among the specimens from the cancer patients compared to the controls while the remaining peaks demonstrated the inverse expression pattern."

Applicants point out page 42 of the specification, where 80 specimens (42 from ovarian specimens and 38 no known cancer specimens) were assayed. It is clear from that passage ovarian samples are assayed, however Example 1 is not as clear. Applicants' claims read on a specific cancer, ovarian cancer, while the support Applicants point out broadly references cancer. Hence, it is not clear if the markers cited in lines 26-31 on page 47 correspond for example to ovarian cancer, prostate cancer or bladder cancer.

Applicants' aver Example 1 clearly indicates higher expression levels of Marker II (9.2kD), Marker III (19.8kD) and 60kD among specimens from the cancer patients, however the particular type of cancer the patients have has not been clearly denoted. As noted in the Request for Continued Examination mailed December 31, 2009 the corresponding figure and description, Figure 2B and figure description found on page 11, lines 25-29 and does not see support

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for the cited amendment. The specification at page 47 notes having three peaks with higher expression and not just one Marker or two as set forth in the claims and the citation also includes a third marker, 60kD, which is not of record in the claims.

The Examiner continues to not find support for the amendment to claim 3 and the rejection is maintained. Applicants are requested to list the page and line numbers within the disclosure that are commensurate with the amendment or delete the new matter.

### ***Conclusion***

5. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

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6. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Alana M. Harris, Ph.D. whose telephone number is (571)272-0831. The Examiner works a *flexible schedule*, however she can normally be reached between the hours of 8 am to 8 pm, with alternate Fridays off.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Larry R. Helms, Ph.D. can be reached on (571) 272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Alana M. Harris, Ph.D.  
22 June 2010

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/Alana M. Harris, Ph.D./

Primary Examiner, Art Unit 1643